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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,436	10/27/2003	Kathleen C.M. Campbell	SIU 7397	8942
321	7590	11/07/2006	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			GEMBEH, SHIRLEY V	
		ART UNIT		PAPER NUMBER
		1614		

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/694,436	CAMPBELL, KATHLEEN C.M.
	Examiner Shirley V. Gembeh	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 July 2006.
- 2a) This action is **FINAL**.                                   2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-20 and 22-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3-20 and 22-34 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All   b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/15/06; 12/7/05; 11/6/04
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 7/17/06, 3/15/06, 12/7/05 and 1/16/04 have been received and acknowledged. The information disclosure statement filed December 07, 2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because item 30 is not a published document so is the information submitted on 7/17/06. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

Also the Epstein and VonDer Maase et al., need the year it was published.

### **Status of claims**

Claims 1, 3-20, 22-34 are pending.

Claims 1, 2-20, 22-34 are rejected.

Receipt is acknowledged of amendment filed 17<sup>th</sup> July 2006. In the amendments filed 17<sup>th</sup> July 2006, claims 1, 3, 20, and 22 were amended. New claims 33 and 34 added.

Claims 1, 3-20, and 22-34 are pending in this application.

Claims 2 and 21 are cancelled.

Claims 1, 3-20, and 22-34 are rejected.

### **The Affidavit**

Declaration of Dr. Sunkara has been fully considered and are not persuasive in light of the current claims. The declaration while impressive does not render the claims patentable because the focus is on oral mocositis and the claims are to reducing

mucositis in a patient. Unless the claims are narrowed to the said declaration, the claims remain to be rejected.

***Response to Arguments***

The response filed 17<sup>th</sup> July 2006 has been received and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in the prior Office action. Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Maintained Claim Rejections - 35 USC § 103***

Claims 1, 3-15, 22-28 and 33-34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell US 6,265,386 B1 in view of Gabrilove US 4,961,926.

Applicant's arguments filed have been fully considered but they are not persuasive.

Applicant argues that the combination of Campbell and Gabrilove does not teach the instant claimed subject matter. Specifically that that the Campbell patent makes no mention of mucositis resulting from any type of insult; and that the patent contains not

the remotest suggestion that methionine or methionine-like moieties would have any value in dealing with mucositis resulting from radiation exposure or administration of an anti-tumor platinum-coordination compound. Thus, from this disclosure alone, it would not have been obvious to a person of skill in the art that methionine would be a protectant for mucositis.

In response to applicant's argument, the compound is administered prior (radiation/anti-tumor platinum-compound), simultaneously and subsequently at col. 19 lines 7-15. It is well known in the art of cancer or chemotherapy to protect the mucosal track prior to administering either the chemotherapy or the radiation either prior of after to prevent patients from emesis. Whether it is explicitly recited by the cited reference or not, the skilled artisan would have been motivated to administer the drug.

Secondly, the claims are directed to the use of methionine-likes moiety. The Campbell patent does sustain a methionine like moiety in its general context. No unobviousness is seen in the combination of the Campbells' patent with that of Gabrilove, more so as Gabrilove teaches a method of preventing mucositis administering methionine colony factor.

Applicant's arguments have been fully considered but they are not persuasive and the rejection in the prior office action is maintained as in the office action of record.

#### ***Claim Rejections - 35 USC § 112***

Claims 1, 3-20 and 22-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating gastrointestinal toxicity, does

not reasonably provide enablement for preventing all types of mucositis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments have been fully considered but are found unpersuasive, the rejection is maintained.

Applicant argues that the in the phase 1 trial D-methionine is the only active agent, also that claims 4, 5, and 6 recite D-methionine, L-methionine, or DL-methionine as the protective agent. Therefore, even if, for argument's sake, claims 1,3, 7-20, and 22-34 were deemed not to be enabled, claims 4, 5, and 6 are nonetheless enabled because the experimentation required to test for each agent's protectant efficacy against mucositis is narrowly limited, and certainly not undue.

In response, Applicant has not provided enough reasoning as to why the claims are enabled. Amending the claims to read free of preventing is partly enabling the claims. However, the using the "methionine-like" compounds presently claimed (see claims 1 and 20), the specification has not supported the wide use of the "methionine-like" compounds presently claimed. As stated in item 2 of the Wands Factors the state of the art involves screening in vitro and in vivo to determine which compounds exhibited the desired pharmacological activities (i.e. what compounds can treat which specific disease). With such a broad terminology, the quantity of experiment will be undue as one has to conduct test on

series of methionine-like compounds to screen which of these methionine-like compounds will reduce mucositis.

After, careful consideration, Applicant's arguments have been fully considered but they are not persuasive.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG  
10/7/06

*Ardin H. Marschel 10/16/06*  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER